Department of Defense
INSTRUCTION

NUMBER 6200.02
February 27, 2008

USD(P&R)

SUBJECT: Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs

References: (a) DoD Directive 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000 (hereby canceled)
(b) DoD Instruction 5025.01, "DoD Directives Program," October 28, 2007
(c) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness," October 17, 2006
(d) Federal Food Drug and Cosmetic Act (FFDCA) (21 U.S.C. 301, et seq.)
(e) through (j), see Enclosure 1

1. PURPOSE

This Instruction:

1.1. Reissues Reference (a) as a DoD Instruction in accordance with the guidance in Reference (b) and the authority in Reference (c).

1.2. Updates policy and assigns responsibility for compliance with Reference (d); sections 1107 and 1107a of title 10, United States Code (U.S.C.) (Reference (e)); Executive Order 13139 (Reference (f)); and Parts 50, 56, 312, Subpart I of Part 314, Subpart G of Part 601 of title 21, Code of Federal Regulations (Reference (g)), for application of FDA rules to force health protection programs of the Department of Defense involving medical products required to be used under an Emergency Use Authorization (EUA) or an investigational new drug (IND) application.

1.3. Incorporates responsibilities of the Secretary of the Army as the Lead Component for the use of medical products under EUAs or IND applications.

Report Documentation Page

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2. APPLICABILITY AND SCOPE

This Instruction:

2.1. Applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the "DoD Components").

2.2. Does not apply to:

2.2.1. Actions by DoD healthcare providers (wherever providing care) that are within standard U.S. medical practice and are not subject to U.S. FDA regulations applicable to investigational medical products.

2.2.2. Uses of medical products by DoD Components, including uses under IND applications, that are not part of a force health protection program.

3. DEFINITIONS

Terms used in this Instruction are defined in Enclosure 2.

4. POLICY

It is DoD policy that:

4.1. Personnel carrying out military operations shall be provided the best possible medical countermeasures to chemical, biological, or radiological warfare or terrorism and other health threats. The DoD Components shall make preferential use of products approved by the FDA for general commercial marketing, when available, to provide the needed medical countermeasure.

4.2. Use of a medical product under a force health protection program pursuant to an EUA or IND application requires approval of the Assistant Secretary of Defense for Health Affairs (ASD(HA)).

5. RESPONSIBILITIES

5.1. The ASD(HA), under the Under Secretary of Defense (Personnel and Readiness), shall have primary responsibility for policy under this Instruction and is authorized to issue Instructions or other guidance for implementation of, and grant exceptions otherwise authorized by law to, this Instruction, and shall monitor implementation of this Instruction.

5.2. The Heads of DoD Components:

5.2.1. May, if at the time of the need under a force health protection program for a medical countermeasure against a particular threat, no satisfactory FDA-approved medical product is available, request approval by the ASD(HA) to use an unapproved product under an EUA or, if an EUA is not feasible, under an IND application. Such requests must:

5.2.1.1. Be justified based on the available evidence of the safety and efficacy of the medical product and the nature and degree of the threat to personnel.

5.2.1.2. Document a high threat for which the use of a drug under an EUA or IND application is needed, consideration of the risks and benefits of use of the drug involved, and compliance with the requirements of this Instruction.

5.2.1.3. Be coordinated with the Chairman of the Joint Chiefs of Staff (and if from the Commander of a Combatant Command, be submitted through the Chairman of the Joint Chiefs of Staff), the Secretary of the Army as Lead Component, and the General Counsel of the Department of Defense.

5.2.2. Shall, when requesting approval to use a medical product under an EUA or IND application, develop, in coordination with the Secretary of the Army, medical protocols, compliant with this Instruction, for use of the product and, if the request is approved, execute such protocols in strict compliance with their requirements.

5.2.3. Shall, when using medical products under a force health protection program pursuant to an EUA, comply with Enclosure 3, Federal Food Drug and Cosmetic Act section 564 (Reference (d)), section 1107a of Reference (e) and applicable FDA requirements.

5.2.4. Shall, when using medical products under a force health protection program pursuant to an IND application, comply with Enclosure 4, section 1107 10 U.S.C., and applicable provisions of References (e) through (g). Requirements applicable to the use of medical products under an IND application do not apply to the use of medical products under an EUA within the scope of the EUA.

5.2.5. May, unless otherwise provided by ASD(HA), make available to Emergency-Essential civilian employees, consistent with DoD Directive 1404.10 (Reference (h)), and/or contractor personnel accompanying the Armed Forces, consistent with DoD Instruction 3020.41 (Reference (i)), who are subject to the same health risk the medical products provided under an EUA or IND application to military personnel under the same terms and conditions, except that the authority to waive an option to refuse under section 1107a of Reference (e) or informed consent under section 1107 of Reference (e) is inapplicable to these personnel.

5.2.6. Shall implement this Instruction and any supplementary guidance from ASD(HA).

5.3. The Secretary of the Army shall serve as Lead Component for development of medical protocols and regulatory submissions to the FDA under this Instruction, and in that role shall:

5.3.1. In concert with the Head of the DoD Component(s) involved and the ASD(HA), develop a specific medical protocol, including appropriate record keeping and reporting of adverse events, and required FDA regulatory submissions for use of the medical product under an EUA or IND application.

5.3.2. Ensure that the Army Medical Research and Materiel Command Human Subjects Research Review Board (HSRRB), under the Surgeon General of the Army, carries out the responsibilities described in paragraph E4.4.

5.3.3. In cases when the medical product has a similar potential use by the Centers for Disease Control and Prevention (CDC) to protect the public's health from bioterrorism or other threats, consult with CDC officials on the potential for collaborative action in pursuing an EUA or IND application.

5.3.4. Prepare annually, in coordination with the Secretaries of the Military Departments and the Chairman of the Joint Chiefs of Staff, a plan for using medical products under EUAs or IND protocols under force health protection programs against health threats when there is no satisfactory approved medical product available. This plan shall establish responsibilities and action timelines to make the best possible medical products available.

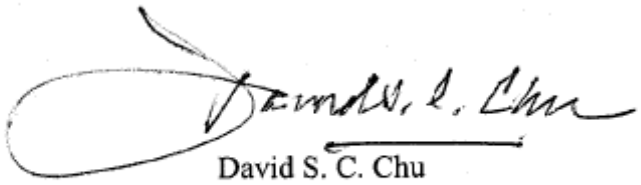
5.4. The Chairman of the Joint Chiefs of Staff shall coordinate and direct activities of the Commanders of the Combatant Commands in the implementation of this Instruction.

6. RELEASABILITY

UNLIMITED. This Instruction is approved for public release. Copies may be obtained through the Internet from the DoD Issuances Web Site at http://www.dtic.mil/whs/directives.

7. EFFECTIVE DATE

This Instruction is effective immediately.



David S. C. Chu
Under Secretary of Defense for
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Enclosures – 4

E1. References
E2. Definitions
E3. Requirements and Procedures Applicable to EUAs
E4. Requirements and Procedures Applicable to IND Applications

E1. ENCLOSURE 1

REFERENCES, continued

(e) Sections 1107 and 1107a of title 10, United States Code
(f) Executive Order 13139, "Improving Health Protection of Military Personnel Participating in Particular Military Operations," September 30, 1999
(g) Title 21, Code of Federal Regulations, Parts 50, 56, 312, Subpart I of Part 314, Subpart G of Part 601, as amended
(h) DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1992
(i) DoD Instruction 3020.41, "Contractor Personnel Authorized to Accompany the U.S. Armed Forces," October 3, 2005
(j) House Conference Report No. 105-736, Conference Report to Accompany Proposed Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, page 685

E2. ENCLOSURE 2

DEFINITIONS

E2.1. Emergency Use Authorization (EUA). An authorization from the FDA under section 564 of Reference (d) with respect to an unapproved product that allows, based on a declaration of emergency by the Secretary of Health and Human Services, the product to be introduced into interstate commerce for use or for the intended use, subject to terms and conditions established by the FDA. An EUA for an unapproved product exempts the product, within the terms of the EUA, from requirements applicable to INDs.

E2.2. Force Health Protection Program. As used in this Instruction, an organized program of healthcare preventive or therapeutic treatment, or preparations for such treatment, designed to meet the actual, anticipated, or potential needs of a group of military personnel in relation to military missions.

E2.3. Investigational New Drug (IND). A drug or biological product subject to the FDA regulations at Part 312 of Reference (g), including:

E2.2.1. A drug not approved or a biological product not licensed by the FDA.

E2.2.2. A drug unapproved for its applied use.

E2.4. Drug Unapproved for Its Applied Use. As provided in section 1107 of Reference (e), an FDA-approved drug or biological product administered for a use not described in the approved labeling of the drug or biological product (referred to in subsection (g)(2)) and for which requirements of use authorization (referred to in subsection (d)(4)) and prior informed consent (referred to in subsection (f)(1)) are applicable by reason of a determination (referred to in subsection (f)(2)) by the Commissioner of Food and Drugs that such use is subject to the investigational new drug requirements of section 505(i) of Reference (d).

E2.4.1. For purposes of the definition in paragraph E2.4, a determination by the Commissioner of Food and Drugs on whether a drug use requires compliance with the investigational new drug requirements of section 505(i) of Reference (d) is conclusive.

E2.4.2. The definition in paragraph E2.4 does not apply to drug uses to which investigational new drug requirements are inapplicable based on standard medical practice in the United States (referred to in Reference (j)). For this purpose, "standard medical practice in the United States" refers, consistent with section 906 of Reference (d) and section 312.2(d) of Reference (g), to the authority of a health care practitioner to prescribe or administer any legally marketed medical product to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

E2.4.3. The definition in paragraph E2.4 does not apply to other drug uses that, as noted in section 1107(f)(2) of Reference (e), have not been determined by the Commissioner of Food and Drugs to be subject to the investigational new drug requirements of section 505(i) of Reference (d).

E2.5. Medical Product. A drug, including a biological product, or a medical device.

E2.6. Particular Military Operation. As used in this Instruction, a military operation or specific military mission or function which involves as part of a force health protection program the use of an IND as a medical countermeasure against any chemical, biological, or radiological warfare or other disease or health threat, and the Commissioner of Food and Drugs has determined that prior individual consent under section 505(i) of Reference (d) is required for use of the IND.

E2.7. Unapproved Product. A medical product that has not been approved by the FDA for general commercial marketing or that the FDA has determined may not be used for its intended purpose without an Emergency Use Authorization or under rules applicable to investigational new drugs or investigational devices.

E3. ENCLOSURE 3

REQUIREMENTS AND PROCEDURES APPLICABLE TO EUAs

E3.1. Declaration of Emergency. Before a medical product may be used under an EUA as part of a force health protection program, the Secretary of Health and Human Services must declare an emergency.

E3.1.1. Domestic Emergency. A declaration of emergency may be based on a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents. Use of a medical countermeasure against such risk may be authorized by an EUA following a declaration of emergency based on a domestic emergency determination.

E3.1.2. Military Emergency. A declaration of emergency may be based on a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents. Use of a medical countermeasure against such risk may be authorized by an EUA following a declaration of emergency based on a military emergency determination.

E3.1.3. Public Health Emergency. A declaration of emergency may be based on a determination by the Secretary of Health and Human Services of a public health emergency that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. Such agent or agents may be a result of an attack by a hostile force or person, accident, or natural occurrence. A disease or disorder, a significant outbreak of an infectious disease, or other emergent public health threat that adversely affects, or has a significant potential to adversely affect, the Armed Forces may be the basis for a determination by the Secretary of Health and Human Services of a public health emergency. Protection of members of the Armed Forces against a disease-causing agent or agents may be authorized by an EUA following a declaration of emergency based on a public health emergency determination.

E3.1.4. Request for Determination. If the ASD(HA) determines that there is a need to request an EUA under a force health protection program and that circumstances support a determination under paragraphs E3.1.1, E3.1.2, or E3.1.3, the ASD(HA) may request a determination by the Secretary of Homeland Security under paragraph E3.1.1, the Secretary of Defense under paragraph E3.1.2, or the Secretary of Health and Human Services under paragraph E3.1.3.

E3.2. Request for EUA. Upon or in anticipation of a declaration of emergency referred to in section E3.1, the ASD(HA) may request from the Commissioner of Food and Drugs an EUA for use of a medical countermeasure within the scope of the declaration of emergency. The request for EUA shall comply with requirements of section 564 of Reference (d) and other requirements of the FDA. Combatant Commanders, through the Chairman of the Joint Chiefs of Staff, and other heads of DoD Components may recommend to the ASD(HA) the submission of requests under this paragraph.

E3.3. Implementation of EUA. DoD Components using medical products under an EUA shall comply with all requirements of section 564 of Reference (d), FDA requirements that are established as a condition of granting the EUA (except as provided in section E3.4 concerning a waiver of an option to refuse), guidance from the Secretary of the Army as Lead Component, and instructions from the ASD(HA).

E3.4. Request to the President to Waive an Option to Refuse. In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients are provided an option to refuse administration of the product, the President may, pursuant to section 1107a of Reference (e), waive the option to refuse for administration of the medical product to members of the armed forces. Such a waiver is allowed if the President determines, in writing, that providing to members of the armed forces an option to refuse is not in the interests of national security. Only the Secretary of Defense may ask the President to grant a waiver of an option to refuse.

E3.4.1. Combatant Commanders, through the Chairman of the Joint Chiefs of Staff, and other heads of DoD Components may recommend to the Secretary of Defense, through the ASD(HA), that the Secretary request a Presidential waiver of an option to refuse administration of an EUA product.

E3.4.2. If the President waives an option to refuse, DoD Components shall comply with all other EUA requirements, including the requirement for information provided to recipients of the EUA product consistent with section 1107a(b) of Reference (e).

E3.5. Pre-EUA Planning. To the extent practicable, Combatant Commanders, through the Chairman of the Joint Chiefs of Staff, and other heads of DoD Components shall coordinate with the Secretary of the Army, as Lead Component, appropriate planning activities, including the development of draft EUA requests to the FDA. The Secretary of the Army shall coordinate with the CDC in the case of potential EUA products of interest to the CDC in anticipation of domestic or public health emergencies and, with the approval of the ASD(HA), with the FDA.

E4. ENCLOSURE 4

REQUIREMENTS AND PROCEDURES APPLICABLE TO IND APPLICATIONS

E4.1. IND Protocol. The protocol shall comply with Part 312 of Reference (g). The protocol shall be approved by the Army Medical Research and Materiel Command Human Subjects Research Review Board (HSRRB), a duly constituted Institutional Review Board under Part 56 of Reference (g), prior to submission to the FDA for review pursuant to Part 312 of Reference (g). Unless the Secretary requests a waiver by the President, the protocol will comply with Part 50 of Reference (g) to the extent it requires the prior informed consent of members receiving the IND. If the request for use of the IND also includes a request for waiver of informed consent under section 1107(f) of Reference (e), the requirements of sections E4.2 through E4.7 shall also apply.

E4.2. Requests By the Secretary of Defense to the President for a Waiver of Informed Consent. Pursuant to section 1107(f) of Reference (e), only the President may grant a waiver of informed consent to use an IND in connection with members' participation in particular military operations. Such a waiver requires a written determination by the President that obtaining informed consent is not in the interests of national security. Only the Secretary of Defense may request that the President grant such a waiver.

E4.3. Standards and Criteria for Requesting a Waiver of Informed Consent. A Combatant Commander may recommend to the Secretary of Defense, through the Chairman of the Joint Chiefs of Staff and in coordination with the Secretary of the Army, as Lead Component, the ASD(HA), and the General Counsel of the Department of Defense, that the Secretary request a waiver by the President of informed consent pursuant to section 1107(f) of Reference (e). Such recommendation shall address all of the standards and criteria set forth in section 50.23(d) of Reference (g) and applicable requirements of Reference (f).

E4.4. Institutional Review Board Approval. An Institutional Review Board (IRB), compliant with Part 56 of Reference (g), shall approve every protocol for the use of an IND under a force health protection program. The Army Medical Research and Materiel Command HSRRB, under the Surgeon General of the Army, is designated as the single IRB responsible for purposes of IRB activities under this Instruction.

E4.4.1. In any case in which a protocol proposes to include a waiver of informed consent under section 1107(f) or Reference (e), a recommendation under section E4.3 that the Secretary of Defense request a waiver by the President shall also address the additional requirements applicable to the HSRRB review and approval of the protocol pursuant to section 50.23(d)(2) and (4) of Reference (g).

E4.4.2. In any case covered by paragraph E4.4.1, the HSRRB must comply with the requirements of section 50.23(d)(3) of Reference(g).

E4.5. Action Required After Waiver of Informed Consent. DoD Components involved in implementation of an IND protocol that includes a waiver of informed consent shall take all necessary actions to ensure proper implementation, including monitoring, Congressional notification, public notifications, reporting to the President, and other actions as may be required by section 1107 of Reference (e), Reference (f), section 50.23(d) of Reference (g), or the ASD(HA).

E4.6. Termination of Waiver. A waiver expires at the end of 1 year (or an alternative time not to exceed 1 year specified by the President) or upon notification by the Secretary to the President that the particular military operation creating the need for the use of the IND has ended, whichever is earlier. A request by the Secretary for a renewal by the President of a waiver must meet the same criteria as the original request.

E4.7. Training and Risk Communication. When using an IND under a force health protection program, the DoD Components involved in implementation shall, consistent with section 1107 of Reference (e), provide prior notice to personnel receiving the drug or biological product and provide all pertinent clinical information to health care providers who administer the IND.

E4.8. Record Keeping on Use of IND and Notice Requirement. The DoD Components involved in implementation shall ensure that medical records of personnel who receive an IND accurately document the receipt of the IND and the notice required by section E4.7.

E4.9. Ongoing Training and Health Risk Communication. The DoD Components involved in implementation shall provide ongoing training and health risk communication on the requirements of using an IND in support of a military operation to all military personnel, including those in leadership positions, during chemical and biological warfare defense training and other training, as appropriate. This ongoing training and health risk communication shall include general information about section 1107 of Reference (e), Reference (f), and section 50.23(d) of Reference (g).

E4.10. Special Additional Training and Health Risk Communication When Informed Consent Is Waived. If the President grants a waiver of informed consent, the DoD Components involved in implementation shall, consistent with Reference (f) and section 50.23(d) of Reference (g), provide training to all military personnel conducting the waiver protocol and health risk communication to all military personnel receiving the specific investigational drug to be administered prior to its use.